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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,344	02/06/2006	Yoav Paltieli	1312PAL-US	5319

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EXAMINER

ROY, BAISAKHI

ART UNIT	PAPER NUMBER
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3737

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/567,344	Applicant(s) PALTIELI ET AL.	
	Examiner BAISAKHI ROY	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/6/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,9,10 and 12-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 9, 10, and 12-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/6/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 9, 10, and 12-14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims are rejected under 35 USC 101 as being directed to non-statutory subject matter because these are method or process claims that do not transform underlying subject matter (such as an article or materials) to a different state or thing, nor are they tied to another statutory class (such as a particular machine). See *Diamond v. Diehr*, 450 U.S. 175, 184 (1981) (quoting *Benson*, 409 U.S. at 70); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978) (citing *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876)). See also *In re Comiskey*, 499 F.3d 1365, 1376 (Fed. Cir. 2007) (request for rehearing *en banc* pending).

Therefore claims need to positively recite in the body of the claim the scanner system used such as the ultrasound scanner system to collect the volume images of the fetus or the claims need to positively recite a transformation step to another state. Since the collection of the ultrasound images may be images stored and recalled from a computer at a later point in time for processing, the step of actually acquiring ultrasound images using an ultrasound scanner system needs to be in the body of the claim. The method steps with image segmentation and display do not lead to the actual transformation of the original image data and therefore the claims do not address a physical transformation to another state or thing.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1 and 2 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6200279.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are directed to a method of monitoring the progress of labor by attaching a plurality of position sensors at various points on the fetus and the mother and monitoring and detecting complications related to the frequency, duration, and strength of contractions, cervical dilation and other factors indicative of any abnormalities during labor. Therefore the patented claims clearly anticipate claims 1 and 2 of this application.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Paltieli (6200279). Paltieli et al. discloses a method for detection of complications during labor to monitor any critical conditions such as the frequency, duration, and strength of uterine contraction and measuring cervical dilation (col. 4 lines 46-64). The steps involve touching a position sensor (PS 1-5, fig. 5) to a point on a fetal presenting part of a fetus in a mother (col. 4 lines 18-23) and capturing a position of the position sensor and touching the position sensor to a set of points on the mother and capturing the position of the position sensor at each point (col. 4 lines 8-9) and detecting a complication.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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4. Claims 12-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Chalana et al. (7087022). Chalana et al. disclose a method for BPD reconstruction (col. 18 lines 17-21) by collecting ultrasound images of a volume containing a fetus along with 3D positional data and multiple 3D views (col. 6 lines 50-52, col. 8 lines 59-63). Multiple data cones are sampled from different anatomical sites at known interval and then combined into a composite image mosaic to present a large uterus in one continuous image (col. 21 lines 17-38). Chalana et al. further detail the steps of registration where geometric transformation or mapping aligns pixels or voxels from one data cone sample of the uterus with viewpoint pixels or voxels from another data cone sampled at a different location. After registration of the two data cones to a common coordinate system, the registered images are fused together producing a reoriented version of the registered data cones (col. 21 lines 39-67). Therefore Chalana et al. teach the translation of pixels of the ultrasonic images to 3D position of those pixels, selecting an image and marking a fetal skull in the image by manually or automatically selecting one of the collected images and marking the contour of the fetal skull image, and projecting the marked fetal skull image onto another ultrasound image representing a different plane in the 3D space (col. 17 lines 59-col. 18 line 55).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paltieli et al. in view of Pathak et al.

Paltieli et al. teach a method for identifying a relevant head plane to pass through a pelvic inlet (col. 3 lines 9-12) by constructing a three-dimensional model of a fetal head and a pelvic inlet (col. 4 lines 24-40), checking dimensions of a set of fetal head planes and their spatial orientation relative to the pelvic inlet (col. 4 lines 12-17) and measuring and monitoring the spatial distance between the fetal BPD and the pelvic inlet. The imaging system shows the descent of the fetal head tip through various stations with respect to the ischial spines 7 or mother's pelvic inlet. Paltieli et al. however do not explicitly teach the step of selecting a plane from the fetal head planes. In the same field of endeavor Pathak et al. disclose a method for identifying a BPD (bi-parietal diameter) pattern in an ultrasound image by identifying an effective ultrasound beam area by placing the ultrasound probe on the mother's abdomen to display the fetus within the womb, the probe is manipulated to image the fetal head 50 at a desired orientation or to capture a cross-section of the fetal head along a longitudinal axis and this cross-section is displayed as a two-dimensional ultrasound image on the display (col. 9 lines 30-40). Therefore the fetal head or face is imaged at a desired orientation. The BPD is then determined which is the average length of the minor axes of inner ellipse 66 and outer ellipse 68 (col. 12 lines 20-22). Therefore the fetal pelvic inlet is modeled by an ellipse. It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Pathak et al. to modify Paltieli et al. such that the generated images may be viewed from different orientations and planes.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BAISAKHI ROY whose telephone number is (571)272-7139. The examiner can normally be reached on M-F (7:30 a.m. - 4p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BR
/Baisakhi Roy/
Examiner, Art Unit 3737